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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,586	11/30/2000	Michael Kock	49100	5846

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
01/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/701,586	KOCK ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 33-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,33-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/2008 has been entered.

Applicant's amendment of claims 1-3, 33-60, in the paper of 10/22/2008, is acknowledged.

Claims 1-3 and 33-60 are at issue and are present for examination.

Applicants' arguments filed on 10/22/2008, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly added claims 3, 34-37, 39-46, 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 34-37, 39-46, 51-60 are indefinite in that it is confusing and unclear as to applicant intent in including the recitation "further comprising..." in each of these claims. The specific basis of this confusion is the reference to "further" in light of each of the claims dependence upon a referenced claim. It is unclear if it is applicants intent that the recited limitations following further are in addition to but outside of those of the referenced base claim, or if the limitations following "further" are in addition to but still including those of the referenced base claim. For the purpose of clarity, if it is applicants intent that each of the dependent claims which recite "further" fall within the scope of the referenced base claim, then it is suggested that applicants delete the "further" reference.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 33-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 and 33-60 are rejected under this statue on the basis that applicants newly added recitation to at least 95% homologous to human PARP2 (SEQ ID NO:2) is not supported by applicants specification at the time of filing and is thus considered new

matter. Applicants comments regarding support for this recitation as presented on page 12 of 14 of applicants arguments presented on 10/22/2008 are acknowledged(i.e. pages 18 and 19 of applicants specification), however, are insufficient in showing support for the newly added recitation.

Claims 1-3 and 33-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a poly(ADP-ribose) polymerase (PARP) homolog comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any poly(ADP-ribose) polymerase (PARP) homolog and functional equivalents thereof which is at least 95% homologous to human PARP2 (SEQ ID NO:2) thereto, and has a functional NAD^+ binding domain with the sequence $PX_n(S/T)GX_3GKGIYFA$, wherein n is an integral value from 1 to 5, and lacks a zinc finger motif with the sequence $CX_2CX_MHX_2C$, wherein M is 28 or 30. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 1-3 and 33-60. In response to the rejection applicants have amended claims 1-3 and 33-60 and argue the rejection as it applies to the newly amended/added claims.

Applicants note the previous position of the office as indicating that "applicants reference to 'at least 85% homologous thereto' is not necessarily limited to an amino acid sequence homology and may be interpreted as 'functional homology', and issue

which does not help applicants meet the requirements of 112 first paragraph. Applicants additionally note that they have amended each of the independent claims 1, 38, and 47, however, applicants make no comment regarding the previously asserted homology limitation as it would apply to applicants similarly amended homology limitation. Applicants merely submit that the instant specification coupled with that knowledge generally available to an ordinary skilled artisan at the time the invention was made, sufficiently enables an ordinary skilled artisan to make and use the invention without undue experimentation.

Applicant's complete argument is acknowledged and has been carefully considered, however, is not found persuasive on for the reasons previously made of record and repeated herein.

Applicants argument continues to be found non-persuasive on the basis that the breadth of applicants claimed genus continues to be broad enough that while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as encompassed by applicants claims and eluded to in applicants arguments requires that one of ordinary skill in the art know or be provided with sufficient guidance for the selection of which of the infinite number of variants have the claimed property. This is especially true in light of the breadth of the claims that are merely limited to those polypeptides having 95% functional homology to the human PARP2 polypeptide. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly

constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting poly(ADP-ribose) polymerase activity; (B) the general tolerance of poly(ADP-ribose) polymerases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a poly(ADP-ribose) polymerase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

As was previously stated, because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the poly(ADP-ribose) polymerase activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus.

The basis of the rejection remains as was previously stated. Applicants reference human poly(ADP-ribose)polymerase is a 570 amino acid sequence protein that is insufficient to enable the breadth of the claimed genus of which applicants are

claiming to any functional equivalent thereof which is at least 85% or 95% homologous (functional homology) thereto and exhibits poly(ADP-ribose)-synthesizing activity and also has a functional NAD+ binding domain comprising the sequence motif $PX_n(S/T)GX_3GKGIYFA$ (SEQ ID NO: 11). Those claimed subgenuses which require additional motif sequences are somewhat more sufficiently enabled, however, remain rejected on the basis that scope of the claimed functional equivalents comprising additional motifs remains overly broad to enable the claimed genus of functional equivalents.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed poly(ADP-ribose) polymerase functional equivalents. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Of note, applicants have not commented to or clearly responded to the reference to “at least 95% homologous” is not necessarily limited to amino acid sequence homology and may be interpreted as "functional homology", an issue which does not help applicants meet the requirements of 112 first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rgh
1/15/2009

/Richard G Hutson/
Primary Examiner, Art Unit 1652